

PERFORMANCE DEMONSTRATION PROGRAM MANAGEMENT PLAN

**Revision 5
April 2012**



**U.S. Department of Energy
Carlsbad Field Office
Office of the National TRU Program**

**This document supersedes revision 4 of
DOE/CBFO-01-3107**

Performance Demonstration Program Management Plan

**DOE/CBFO-01-3107
Revision 5**

April 2012

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ACRONYMS

CAR	Corrective Action Report
CBFO	Carlsbad Field Office
CTAC	Carlsbad Field Office Technical Assistance Contractor
CCA	Compliance Certification Application
CRA	Compliance Recertification Application
DOE	U. S. Department of Energy
HSG	headspace gas
HWFP	Hazardous Waste Facility Permit
MP	Management Procedure
NDA	nondestructive assay
PDP	Performance Demonstration Program
QA	quality assurance
QAPD	Quality Assurance Program Document
RCRA	Resource Conservation and Recovery Act
SGV	standard gas vendor
SPC	sample preparation contractor
TRU	transuranic
WAC	Waste Acceptance Criteria
WAP	Waste Analysis Plan
WIPP	Waste Isolation Pilot Plant

**Significant Changes to the
Performance Demonstration Program Management Plan, Revision 4**

General

1. Section 2 was revised to improve organizational roles and responsibilities.
2. Editorial changes were made for technical clarity.
3. Section 3 was revised to clarify training requirements.

1.0 INTRODUCTION

To demonstrate compliance with the U.S. Department of Energy (DOE) Waste Isolation Pilot Plant (WIPP) waste characterization program, each testing and analytical facility performing waste characterization activities participates in the Performance Demonstration Program (PDP). The PDP serves as a quality control check against expected results and provides information about the quality of data generated in the characterization of waste destined for WIPP. Single blind audit samples are prepared and distributed by an independent organization to each of the facilities participating in the PDP. The PDP consists of the analysis of simulated headspace gases (HSG), analysis of solids for Resource Conservation and Recovery Act (RCRA) constituents, and analysis for transuranic (TRU) radionuclides using nondestructive assay (NDA) techniques. Because the analysis for TRU radionuclides uses NDA techniques to conduct measurements of wastes in drums and in standard waste boxes, four PDP plans are required to describe the activities of the three PDP elements. Within the DOE Carlsbad Field Office (CBFO), the Office of the National TRU Program oversees the elements of the PDP as described in the current revisions of the following plans:

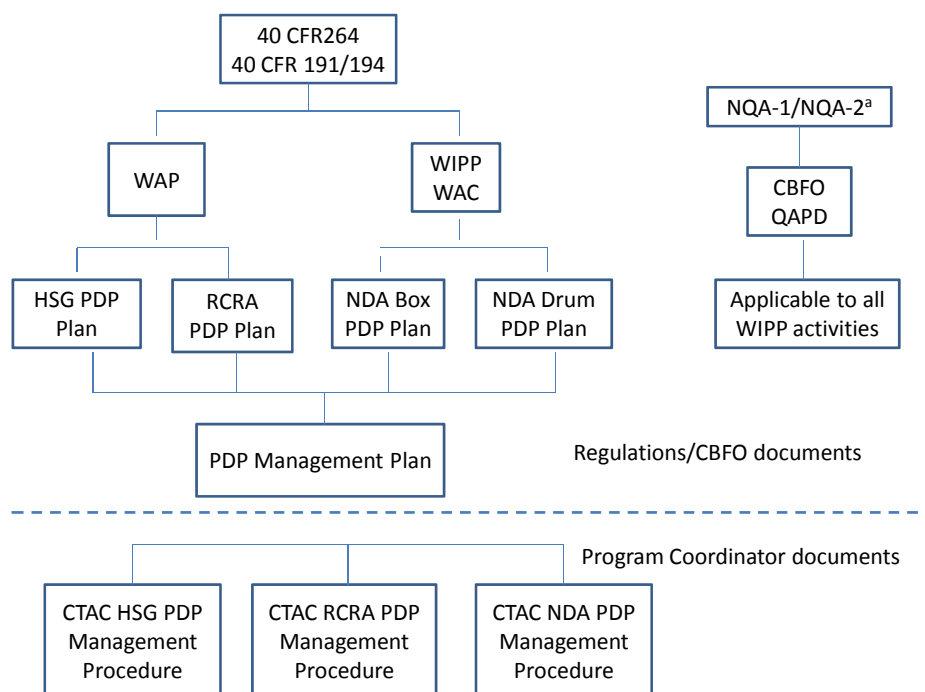
- DOE/CBFO-01-1005, *Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program* (Drum NDA PDP Plan)
- DOE/CBFO-95-1076, *Performance Demonstration Program Plan for Analysis of Simulated Headspace Gases* (HSG PDP Plan)
- DOE/CBFO-95-1077, *Performance Demonstration Program Plan for RCRA Constituent Analysis of Solidified Wastes* (RCRA PDP Plan)
- DOE/CBFO-01-1006, *Performance Demonstration Program Plan for Nondestructive Assay of Boxed Wastes for the TRU Waste Characterization Program* (Box NDA PDP Plan)

The purpose of this management plan is to identify how the requirements applicable to the PDP are implemented during the management and coordination of PDP activities. The CBFO has tasked the CBFO Technical Assistance Contractor (CTAC) to serve as Program Coordinator for the PDP. The other participants in the program (organizations that perform site implementation and activities under CBFO contracts or interoffice work orders) are not covered under this management plan. Those activities are governed by the organization's quality assurance (QA) program and procedures or as otherwise directed by CBFO.

The primary documents governing the conduct of the PDP elements are:

- CBFO-94-1012, *Quality Assurance Program Document* (QAPD)
- *Waste Isolation Pilot Plant Hazardous Waste Facility Final Permit* (HWFP) (NM4890139088-TSDF, as modified)
- HWFP Waste Analysis Plan (WAP)
- DOE/CAO-1996-2184, *Compliance Certification Application* (CCA)
- DOE/WIPP 09-3424, *Compliance Recertification Application-2009* (CRA)
- DOE/WIPP-02-3122, *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant* (WAC)

These documents require each of the analytical laboratories and NDA systems that provide data for the characterization of TRU waste for disposal at WIPP to participate in the applicable PDP element. The four PDP plans implement the applicable general requirements of the QAPD. The RCRA and HSG PDP Plans implement applicable technical and quality requirements of the WAP, and the two NDA PDP Plans implement the requirements of the CCA, CRA, and the WAC. The management and coordination of the PDP are conducted in full compliance with applicable requirements. The relationship of the applicable documents is illustrated in Figure 1. As shown in the figure, the PDP Plans are higher-level documents than the PDP Management Plan. Therefore, in cases where requirements specified in these plans conflict, the element-specific PDP Plan takes precedence.



^aThe complete reference for the applicable documents is: ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7 to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1).

Figure 1. Document Hierarchy

Figure 1 also shows the relationship to the Program Coordinator documents that serve as work instructions for each PDP element and implement the requirements of the applicable PDP plan(s) and this management plan. These procedures shall be reviewed by the CBFO Office of the National TRU Program PDP Appointee to ensure adequate implementation of the respective PDP plans.

This management plan will be promptly reviewed and revised as necessary to incorporate any changes in CBFO documents that affect the program, including the QAPD, WAP, WAC, CBFO management procedures (MPs), or PDP plan(s). The review of and any resultant changes to this management plan will be documented.

2.0 ORGANIZATION AND RESPONSIBILITIES

The CBFO is responsible for ensuring the implementation of this plan and assigns an individual as the PDP Appointee to provide technical oversight and coordination for the program. The CBFO PDP Appointee is the reviewing and approving authority for all PDP activities. The Program Coordinator designates the PDP Manager and administers PDP functions to qualify testing and analytical facilities that are active in waste characterization for the participating TRU waste sites. The CBFO, supported by the Program Coordinator, evaluates and approves individual facility performance for participation in the WIPP TRU waste disposal characterization program.

The organizational structure for implementing the PDP requirements is shown in Figure 2, and the responsibilities for implementing and managing the program within the contractor organization are discussed below.

2.1 Program Coordinator PDP Manager

The Program Coordinator assigns overall PDP responsibilities to the PDP Manager, who ensures that all PDP responsibilities identified in the PDP plans, and those implemented through this program management plan and the applicable CBFO MPs, are met. The PDP Manager:

- Routinely evaluates PDP performance in support of the CBFO and reviews and approves outgoing documentation associated with the PDP.
- Reports to the Office of the National TRU Program PDP Appointee and oversees and coordinates activities within the three PDP areas.
- Serves as the central point-of-contact for technical issues, scheduling, assessment interfaces, quality improvement, and other matters affecting the PDP.
- Designates a PDP Coordinator for each of the PDP elements.
- Provides prime direction to PDP Coordinator personnel for each of the PDP elements, prepares corrective documentation, and coordinates the preparation of PDP budget documents to ensure that adequate resources are available to meet program goals and milestones.

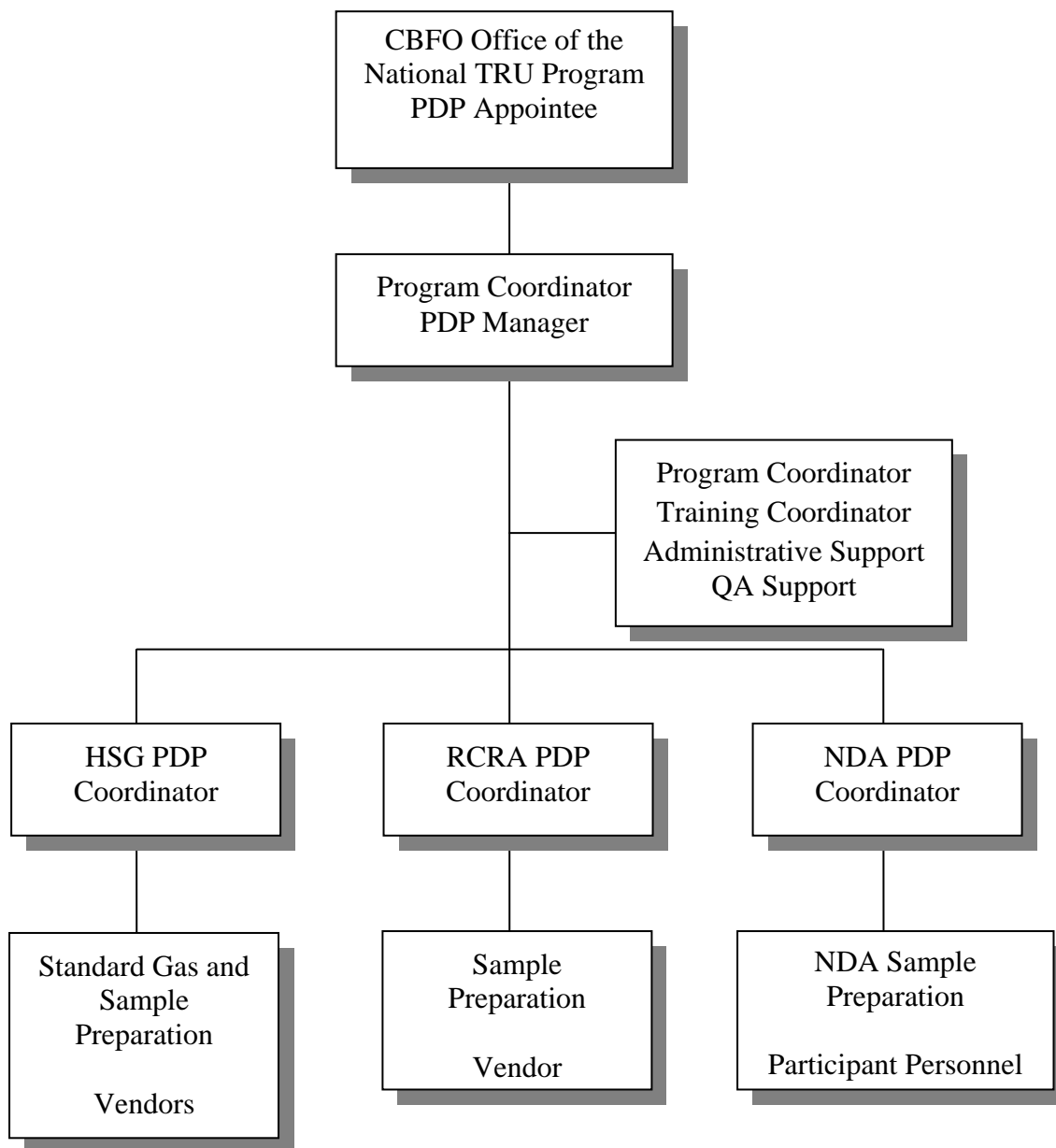


Figure 2. PDP Organizational Structure

2.2 PDP Coordinators

Each PDP Coordinator is responsible for accomplishing the day-to-day tasks associated with the implementation of the PDP management plan. Tasks are defined in each of the PDP plans and are conducted in accordance with a PDP element-specific procedure or work instruction prepared by each PDP Coordinator and approved by the PDP Manager. PDP Coordinators are responsible for ensuring quality and for promptly reporting all potential conditions adverse to quality to the PDP Manager for evaluation and action in accordance with CBFO MP 3.1, *Corrective Action Reports*.

3.0 TRAINING AND QUALIFICATION

Personnel involved in PDP management activities shall be qualified and trained as follows.

At a minimum, the PDP Manager and PDP Coordinator personnel shall have at least a bachelor's degree in science or engineering and at least five years of professional experience related to the type of PDP activities that are being coordinated. Qualification and contractor training documentation shall be entered into the CBFO records system. The PDP Manager is responsible for selecting qualified personnel and ensuring that they complete the appropriate training.

The minimum required training elements for PDP personnel include reading the current revision of the documents listed in Table 1 and any other documents identified as required reading by the PDP Manager. Completion of the reading requirement shall be documented on a form such as shown in Attachment 1, or on an equivalent form. An equivalent form includes "read and sign" notices distributed to PDP personnel by the Program Coordinator's Training Coordinator to track training updates as documents are revised and formally issued. The Training Coordinator shall ensure that documentation of completed training is maintained in QA records in accordance with CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*.

Table 1. Required Training Elements for PDP Personnel

Current Version of Requirements Document	PDP Manager	NDA PDP Coordinator	RCRA PDP Coordinator	HSG PDP Coordinator
CBFO QAPD (CBFO-94-1012)	X	X	X	X
WIPP RCRA HWFP WAP, including Attachments 1 and 3	X	NR	X	X
WIPP WAC (DOE/WIPP-02-3122)	X	X	NR	NR
CBFO PDP Management Plan (DOE/CBFO-01-3107)	X	X	X	X
CBFO NDA PDP Plan for Boxed Wastes (DOE/CBFO-01-1006)	X	X	NR	NR
CBFO NDA PDP Plan for Drummed Wastes (DOE/CBFO-01-1005)	X	X	NR	NR
CBFO HSG PDP Plan (DOE/CBFO-95-1076)	X	NR	NR	X
CBFO RCRA PDP Plan (DOE/CBFO-95-1077)	X	NR	X	NR
CBFO MP 1.2, "Selection of Quality Levels"	X	X	X	X

CBFO MP 3.1, "Corrective Action Reports"	X	X	X	X
CBFO MP 4.5, "Generating, Receiving, Storing, and Controlling Active CBFO Program Records"	X	X	X	X
CTAC MP 2.7, "Conduct of the Nondestructive Assay Performance Demonstration Program"	X	X	NR	NR
CTAC MP 2.5, "Conduct of Headspace Gas Performance Demonstration Program"	X	NR	NR	X
CTAC MP 2.6, "Conduct of RCRA Performance Demonstration Program"	X	NR	X	NR
CTAC MP 7.1, "Procurement"	X	X	X	X
CTAC MP 16.1, "Corrective Action Reporting"	X	X	X	X
CTAC MP 17.1, "Quality Assurance Records"	X	X	X	X
NR=not required				

4.0 QA GRADING ACTIVITIES

The CBFO, assisted by the Program Coordinator, will perform PDP activity grading in accordance with CBFO MP 1.2, *Selection of Quality Levels*, and will also document and retain the evaluation as required by MP 1.2. The grading applies only to the specific controls placed on the activity and not the requirements. In no case will requirements be graded out of the program.

5.0 PROCUREMENT

CTAC, as the Program Coordinator, implements procurements for continuing operations of the PDP. These may include procurements for:

- Consultant support contracts to obtain the services of an individual with extensive experience in developing and maintaining operations of the PDP
- Supplier procurement contracts with commercial laboratories for sample preparation and verification support efforts or with commercial suppliers for manufacture of PDP equipment and accessories (e.g., NDA PDP drums, boxes, and the spare parts associated with these items)

Procurements may involve subcontractors who have previous, documented, and acceptable performance in support of the PDP. No procurement will exceed the scope of work currently being performed. All applicable procurement requirements of the QAPD shall be met. PDP procurements conducted by the Program Coordinator will be in accordance with procedures written to support the procurement function and will be performed as follows.

Typically, procurement documentation is prepared by the applicable PDP Coordinator and reviewed and approved by the PDP Manager. The PDP Manager, Program Coordinator's Contracts Administrator, and a QA support individual shall ensure that all applicable elements required by the

QAPD are appropriately incorporated in the procurement documents. The PDP Manager is responsible for final review and approval of procurement documentation and for ensuring that the applicable QAPD procurement requirements and the contractor organization's procurement requirements are addressed. The reviews and approvals shall be documented in accordance with the Program Coordinator's procedure for procurement.

The Program Coordinator's Contracts Administrator, in conjunction with the applicable PDP Coordinator, shall select the procurement source and document the basis for selection.

Suppliers will be selected consistent with the requirements for supplier selection specified in the QAPD. Prospective suppliers shall initially be evaluated and selected on the basis of documented criteria and the PDP Manager and/or applicable PDP Coordinator shall verify that approved suppliers continue to provide acceptable items and services. Supplier selection shall be based on evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements by performing one or more of the following elements:

1. An evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use.
2. An evaluation of the supplier's current QA documentation, supported by any documented qualitative and quantitative information.
3. An evaluation of the supplier's technical and QA capability, based on an evaluation of the supplier's facilities, personnel, and quality program implementation.

When a supplier has previously and successfully supported the PDP Program, a surveillance or an evaluation of the supplier's continued performance shall be performed at least every three years. Evaluations are performed of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use and of the current QA documentation, supported by any documented qualitative and quantitative information, in accordance with approved implementing procedures to determine continued satisfactory performance. These surveillances or evaluations shall be performed more frequently if performance problems are encountered or other situations develop that suggest a surveillance or an evaluation is needed.

Supplier bids shall be evaluated based upon the following criteria:

- Conformance to the procurement documents (statement of work)
- Technical considerations
- QA requirements
- Prospective supplier's personnel, production capability, past performance, and any exceptions taken. All unacceptable quality conditions shall be resolved prior to order placement.

The applicable PDP Coordinator will perform and document an annual review of each subcontracted supplier or conduct receipt inspections to ensure the supplier is performing acceptably. Documentation of this review may be in the form of a formal report or a renewed contract for services in the upcoming year. If the results of the review indicate the need, an onsite assessment will be performed.

The responsible PDP Coordinator shall review and document acceptance of the supplier's deliverables to ensure that they meet the procurement requirements. The PDP Coordinator shall also review and approve the disposition of any PDP supplier nonconformance documentation.

Changes to procurement documents require the same degree of control and review as the original procurement documents. Procurement documents and other records generated during the procurement of PDP items and services are QA records. QA records shall be processed in accordance with CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*. PDP procurement QA records have been determined to be nonpermanent.

6.0 NONCONFORMANCES AND CORRECTIVE ACTION

A corrective action report (CAR) will be written in accordance with CBFO MP 3.1, *Corrective Action Reports*, whenever a condition adverse to quality is identified. PDP support supplier performance is measured as an inherent part of each RCRA and HSG PDP cycle. In the RCRA PDP, the sample preparation contractor (SPC) manufactures the PDP samples and conducts verification analyses to certify the known analyte concentrations in each of the PDP samples. In the HSG PDP, a standard gas vendor (SGV) manufactures and certifies custom gas mixes which are then used by the SPC to prepare PDP samples in Summa[®] canisters. The SPC conducts confirmatory analyses of the analyte concentrations in each of the PDP samples following the transfill operation. When the majority of participant results agree with the known analyte concentrations, the supplier performance is further confirmed. However, if all TRU waste sites report a different result, with a similar bias, it may indicate a supplier problem with the sample preparation and/or verification analysis. In such cases, in accordance with the RCRA and HSG PDP Plans, the result for any such analyte(s) may be discarded, and a CAR will be initiated. When a CAR is initiated, appropriate remedial actions, investigation, root cause determination, and actions to preclude recurrence will be implemented in accordance with CBFO MP 3.1.

7.0 PDP QA RECORDS

PDP QA records are designated as nonpermanent. All PDP documents classified as QA records that are prepared by the contractor in its PDP support capacity shall be transmitted to the CBFO for appropriate management and retention. Documentation in process is maintained with reasonable protection prior to completion. (In accordance with the CBFO QAPD, documentation is not considered to be a QA record until it has been completed.) CBFO accepts the data, approves the final issuance of results and other documentation, and processes the records in accordance with CBFO MP 4.5.

Records generated by participants that are associated with PDP analyses and measurements are considered QA records and must be maintained by the individual participant in accordance with the CBFO QAPD (section 1.5, Records).

PDP QA records are identified in each PDP plan. For each of the PDP elements, the corresponding procedure or work instruction should include the specific records that are generated during PDP implementation. QA records management, including disposition, when applicable, will be maintained in accordance with CBFO MP 4.5.

8.0 PDP ASSESSMENTS

In addition to the routine reviews of internal activities by the PDP Manager during the conduct of the PDP cycles, the Program Coordinator shall ensure management assessments are conducted periodically. CBFO performs assessments of the PDP on a periodic basis, not to exceed three years. These assessments are performed in accordance with the requirements of the CBFO QAPD.

9.0 PDP SOFTWARE REQUIREMENTS

Any PDP software used for scoring analytical and other measurement results (i.e., spreadsheets developed using commercial software such as Microsoft Excel) shall be in conformance with QAPD requirements. Commercial software is exempt from the software control requirements of section 6.0; however, the applications of such commercial software are not exempt from the software control requirements of section 6.0.

Spreadsheet applications produced using the software shall be fully documented and validated according to applicable QAPD requirements. The PDP Coordinators are responsible for ensuring that any spreadsheet development and use is properly documented and validated.

Any spreadsheet developed and used for a PDP activity to obtain final results shall be identified with a revision or version number. Since these spreadsheets will be used only by the coordinators and possibly a trained backup individual, software distribution and control does not pose a concern. Any newly developed spreadsheets used to obtain final results and any changes to existing spreadsheets used to obtain final results shall be validated by comparing software results with hand calculations or other appropriate means. Any subsequent revision shall be revalidated by comparing the new results with the values obtained before the change or through some other comparison. The specific validation tests shall be designed to cover the entire range of interest and shall be documented. Records associated with validation of such scoring spreadsheets shall be maintained in the CBFO records system.

If an Excel spreadsheet is used to obtain final results, the calculations performed by the spreadsheet will be verified and validated by verifying that the spreadsheet works correctly over the expected range of the input variables, and documented by issuing a memo record containing the following information to the CBFO PDP Appointee:

- Name and version of the software used
- Name and version number (required) of the spreadsheet, and the name of the developer
- Scope of the computation
- Data entry process description
- List and definition of named variables
- Definition of complex formulas (i.e., formulas not easily deduced by inspection of the spreadsheet or macro)
- Documentation of the verification of the software (by hand calculation or other means)
- An electronic disk copy of the spreadsheet set up to run one of the documented verification tests
- Inputs, output results, and ancillary data (if used)

If spreadsheets containing formulas are used to obtain preliminary results, the results of all formulas used in the spreadsheet must be verified and documented prior to using the results as final data.

10.0 REFERENCES

- DOE/CBFO-94-1012, *Quality Assurance Program Document*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CAO-1996-2184, *Title 40 Part 191, Compliance Certification Application for the Waste Isolation Pilot Plant*, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO TP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 7.1, *Procurement*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 3.1, *Corrective Action Reports*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 1.2, *Selection of Quality Levels*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 10.2, *Surveillances*, current revision, U.S. Department of Energy Carlsbad Field Office
- CBFO MP 10.3, *Audits*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/WIPP-02-3122, *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-01-1005, *Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-95-1076, *Performance Demonstration Program Plan for Analysis of Simulated Headspace Gases*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-95-1077, *Performance Demonstration Program Plan for RCRA Constituent Analysis of Solidified Wastes*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/CBFO-01-1006, *Performance Demonstration Program Plan for Nondestructive Assay of Boxed Wastes for the TRU Waste Characterization Program*, current revision, U.S. Department of Energy Carlsbad Field Office
- DOE/WIPP 09-3424, *40 CFR Part 191 and 194, Compliance Recertification Application for the Waste Isolation Pilot Plant*. U.S. Department of Energy Carlsbad, New Mexico
- NM4890139088, *Hazardous Waste Facility Final Permit*, as modified, New Mexico Environment Department, Santa Fe, New Mexico

**Attachment 1—Example Form for Documentation of Completion of Required Training
CTAC Training Requirements for Performance Demonstration Program (PDP)
Program Management Support to CBFO**

NAME: _____ **POSITION:** _____

1. Prior to performing quality-affecting work, training must be completed and documented on this form.
2. Specific training requirements for your position are identified by an “X” in the “Req.” column.
3. Be sure to document the training for the last revision of the document; list the revision number.
4. List the Training Type(s) used:
C = Classroom
R = Reading
B = Briefing
T = Test Required at Completion
5. As each training element is completed, sign and date in the columns provided for that element.

Training Element	Req.	Rev.	Training Type(s)	Signature	Date
CBFO QAPD (CBFO-94-1012)					
WIPP RCRA HWFP WAP, including Attachments 1 and 3					
WIPP WAC					
CBFO HSG PDP Plan (DOE/CBFO-95-1076)					
CBFO RCRA PDP Plan (DOE/CBFO-95-1077)					
CBFO Drum NDA PDP Plan (DOE/CBFO-01-1005)					
CBFO Box NDA PDP Plan (DOE/CBFO-01-1006)					
CBFO PDP Management Plan (DOE/CBFO-01-3107)					
CTAC MP 2.5, “Conduct of Headspace Gas Performance Demonstration Program”					
CTAC MP 2.6, “Conduct of the RCRA Performance Demonstration Program”					
CTAC MP 2.7, “Conduct of the Non-Destructive Assay Performance Demonstration Program”					
CBFO MP 1.2 ICN#1, “Selection of Quality Levels”					
CBFO MP 3.1, “Corrective Action Reports”					
CBFO MP 4.5, “Generating, Receiving, Storing, and Controlling Active CBFO Program Records”					
WIPP General Employee Training					
Other					
Other:					

Training Assigned By: _____

Date: _____

Training Completion Verified By: _____

Date: _____